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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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16

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/333,966

Applicant(s)

Yu et al.

Examiner

John Ulm

Art Unit

1646



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on May 16, 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 27-46 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 27-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
- 18) ☐ Interview Summary (PTO-413) Paper No(s).
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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- 1) Claims 27 to 46 are pending in the instant application.
- 2) The request filed on 16 May of 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/333,966 is acceptable and a CPA has been established. An action on the CPA follows.
- 3) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 4) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 5) Claims 27 to 46 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility for those reasons of record in section 2 of Paper Number 5. There is no evidence of record that a receptor protein of the claimed invention is associated in any way with a specific disease or disorder. Apoptosis is not a disease or disorder. It is a fundamental process known to occur in multicellular organisms. However, there is no reference of record which describes the employment of a death domain-containing receptor to effect apoptosis for clinical effect. The most notorious death domain-containing receptor known in the art at the time of the instant invention is a tumor necrosis factor (TNF) receptor. The art has yet to describe the successful employment of that TNF receptor as the target of a clinically useful ligand. This is because the concentration of agonist needed to induce tumor necrosis is several fold higher than the dosage required to kill the organism containing that tumor. In the instant case, the specification does not

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disclose the identity of even a single compound which can act as an agonist or antagonist of the disclosed receptor. Therefore, one has no way of knowing what the effect of the administration of such a compound will have on an organism. A patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentec, Inc. v. Novo Nordisk*, 42 USPQ 2d 100, (CAFC 1997), the court held that:

“[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable” and that “[t]ossing out the mere germ of an idea does not constitute enabling disclosure”. The court further stated that “when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art”, “[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement”.

The instant specification is not enabling because one can not following the guidance presented therein and employ the receptor protein described therein in a specific and substantial manner without first making a substantial inventive contribution.

Applicant has cited the Warzocha et al. publication (Biochem. Biophys. Res. Com. 242:376-379, 1998) as showing that the receptor of the instant invention is useful as a disease marker. This publication clearly shows that the claimed invention is useful in this capacity. However, an invention must be patentable at the time that an application is filed (“in currently

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available form"). Applicant can not rely upon subsequent discoveries by themselves or others to perfect the claimed invention. The assertions contained on page 38 of the instant specification are not specific. The fact that Applicant included lymphomas in a long list of causally unrelated diseases does not constitute either a specific or credible assertion on a utility for the claimed protein. At the time that the instant application was filed, there was no credible evidence that a protein of the instant invention was associated in any way with any one or more of those diseases or disorders.

6) Claims 27 to 46 also stand rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a credible, substantial and specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

35 U.S.C. § 120 states that:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

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7) Claims 27 to 46 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by each of the Chinnaiyan et al. (SCIENCE 274:990-992, 08 Nov. 1996, of record) and Kitson et al. (NATURE 384:372-375, 28 Nov. 1996, of record). Each of these publications provided a written description of the claimed protein. Applicant is advised that the instant application can only receive benefit under 35 U.S.C. § 120 from an earlier application which meets the requirements of 35 U.S.C. § 112, first paragraph, with respect to the now claimed invention. Because the instant application does not meet the requirements of 35 U.S.C. § 112, first paragraph, for those reasons given above and it is a divisional of application Serial Number 08/815,469, the prior application also does not meet those requirements and, therefore, is unavailable under 35 U.S.C. § 120.

8) Applicant's arguments filed 20 February of 2001 have been fully considered but they are not persuasive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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JOHN ULM  
PRIMARY EXAMINER  
GROUP 1800